EXHIBIT 4

NATSUMI CHIKAYASU FOR STAT

A STAT INVESTIGATION

Health Care's *Colossus*

How UnitedHealth turned a questionable artery-screening program into a gold mine




By Casey Ross , Lizzy Lawrence , Bob Herman , *and* Tara Bannow

Aug. 7, 2024

This is the second in a periodic series about how UnitedHealth Group wields its unrivaled physician empire to boost its profits and expand its influence. Read Part 1.

The nation's largest health care company pressed thousands of its clinicians to use a thinly tested medical device to screen people for artery disease, dramatically boosting payments from the federal government for years even though many of the patients were not sick, a STAT investigation found.

The result was a torrent of sometimes questionable diagnoses of peripheral artery disease. Each one allowed the company, UnitedHealth Group, to claim thousands of dollars of extra payments tied to patients covered under Medicare Advantage, the increasingly popular version of Medicare run by private insurers. In many cases, those diagnoses were not medically useful, either because they were false positives or because they flagged early-stage disease, which isn't typically treated, according to nine clinicians.

UnitedHealth was perfectly positioned to invent a national screening program and profit from it. Over the last two decades it has assembled an unrivaled collection of physicians — some 90,000 doctors in all — and used this empire to pad its bottom line, as STAT previously reported. At the same time, it has cemented its lead as the largest Medicare Advantage insurer. The full story of the company's sweeping vascular disease screening program, detailed here for the first time, reveals how UnitedHealth has used its growing dominance across the health care system to its own benefit — and to the detriment of doctors, patients, and taxpayers.

"The corporation views patients as entities that have money attached to their bodies," said Michael Good, a retired physician who worked at a Connecticut practice where UnitedHealth tested older patients with the device, called QuantaFlo. "They want to use the clinicians to mine the money that lies within the bodies of the patient."

The Centers for Medicare and Medicaid Services began cracking down on the aggressive diagnosis of peripheral artery disease in 2024, removing a diagnostic code from its payment formula that allowed UnitedHealth and other insurers to get extra reimbursement for diagnosing patients even if they weren't experiencing symptoms. In the following months, diagnoses of the condition began to decline.

In a statement, UnitedHealth defended its screening program.

"Screening patients with an increased risk for PAD aligns with guidance provided by the American Heart Association and the American College of Cardiology, and helps to identify and treat an under-diagnosed condition that, if left unmonitored and untreated, can lead to serious health consequences," UnitedHealth's statement said. "QuantaFlo is one FDA cleared tool providers may use, based on their independent clinical judgment, to assist in diagnosing patients with an increased risk for PAD and help ensure they receive appropriate follow-up care."

STAT's investigation is based on interviews with patients, vascular disease experts, and more than a dozen current and former clinicians at practices acquired by UnitedHealth across the country. It also included a review of internal communications, court records, scientific studies, and corporate documents that describe UnitedHealth's diagnostic coding practices and interactions with front-line caregivers. Some of the clinicians asked for anonymity out of concern for professional or legal repercussions from UnitedHealth.

More on UnitedHealth

- **Part one of this series** looked at how UnitedHealth leveraged its physician empire to squeeze profits out of patients. Here's a video explainer on how it works.
- **The country's biggest** private health insurer, UnitedHealthcare, is in a contract dispute with its biggest hospital chain, HCA Healthcare.
- **Our 2023 "Denied by AI" UnitedHealth series** began with how Medicare Advantage plans use algorithms to cut off care for seniors. The series continued with a story on internal dissent at UnitedHealth, and pressure to follow the algorithm on discharge decisions. The final installment looked at the use of secret rules to restrict rehab care.

Doctors whose practices were acquired by the company's Optum subsidiary said they received hours of training on how to document patients' illnesses and increase payments from Medicare. Some clinicians previously told STAT they were pushed to document conditions they didn't believe applied to their patients. Part of their compensation was tied to the number of diagnoses they submitted for chronic conditions, including peripheral artery disease.

At the same time, they said they received no additional instruction or resources to improve care for patients with the condition. In some cases, the patients themselves only learned of the diagnosis in reviewing their own medical charts, triggering panicked calls to their doctors about the appearance of an ominous-sounding illness.

Peripheral artery disease affects between 8 million and 12 million patients a year in the U.S. and is particularly prevalent among those over age 65. It results from the gradual buildup of plaque in the arteries, typically reducing blood flow to a patient's legs and causing cramping or pain in the calf during exercise. Specialists in treating the condition said it is underdiagnosed, particularly in low-income communities and among Black people. If left untreated, it can eventually lead to amputations and even become life-threatening.

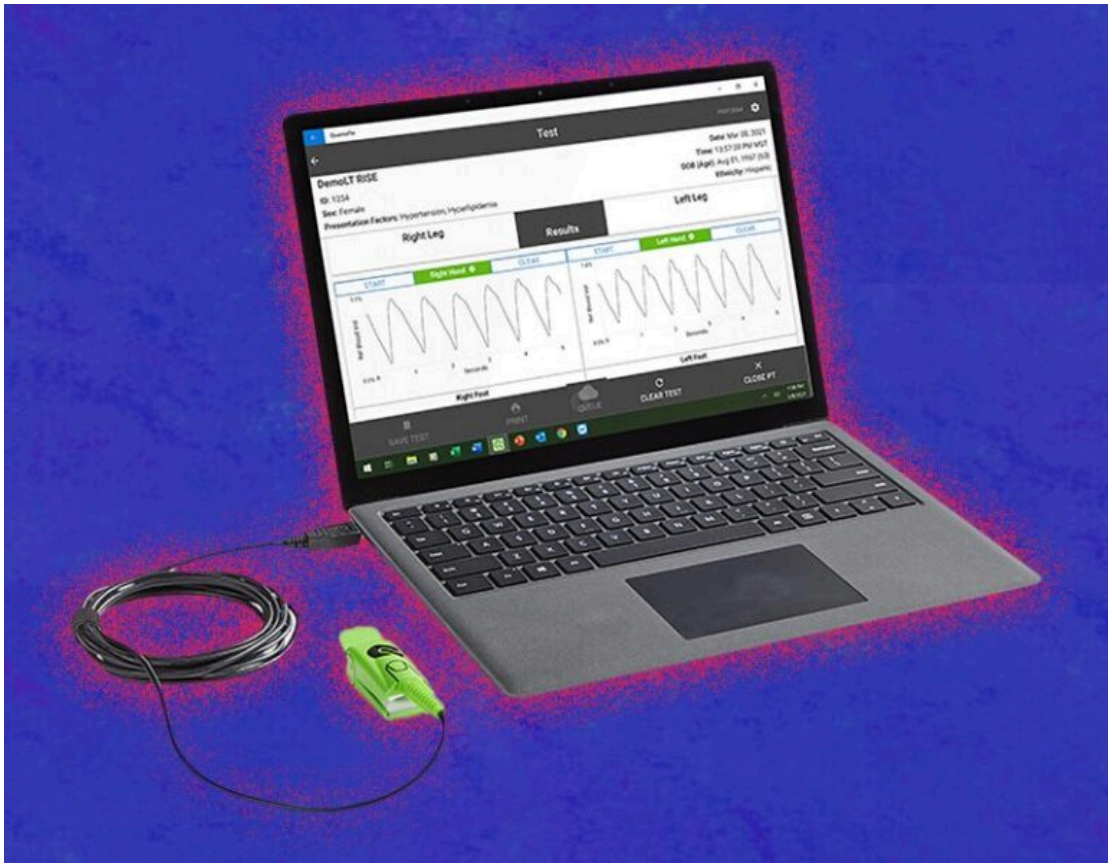
Still, the value of screening large numbers of patients is unclear. The U.S. Preventive Services Task Force, an independent panel that advises primary care physicians, does not recommend screening in patients without symptoms, due to a lack of evidence that early detection and treatment leads to better outcomes. The American Heart Association and the American College of Cardiology call for performing a thorough medical history and workup to detect signs of peripheral artery disease among patients over age 65, as well as younger patients with risk factors such as a history of diabetes, smoking, high cholesterol, or high blood pressure.

UnitedHealth does not apply those recommendations consistently. In a guidance document for clinicians who conduct visits with patients in their homes — a program called HouseCalls — the company cites the cardiology guidelines to support screening for peripheral artery disease in patients without symptoms.

But guidance to medical reviewers who decide whether UnitedHealth insurance plans should pay for services, advises against screening for peripheral artery disease in patients without symptoms. The guidance to medical reviewers states that patients with abnormal pulses may receive a standard test known as the ankle brachial index, a well-established method of identifying artery disease that relies on blood pressure measurements taken at the ankle and arms.

UnitedHealth's screening in patients' homes and primary care clinics doesn't use that technology. Instead the company relies on QuantaFlo, a relatively new device. Cleared in 2015 through a Food and Drug Administration pathway that requires limited clinical testing, QuantaFlo calculates artery blood volume

by measuring reflected infrared light through sensors placed on a patients' fingers and toes. It was cleared as a tool to aid clinicians in diagnosing PAD, but not as a standalone diagnostic device. QuantaFlo is backed by a slim body of evidence generated by its manufacturer, California-based Semler Scientific, and customers.



Cleared in 2015 through an FDA pathway that requires limited testing, the lime-green QuantaFlo device calculates artery blood volume by measuring reflected infrared light through sensors placed on a patients' fingers and toes. *STAT*

One study sponsored by Semler that describes the development of QuantaFlo found that the device is comparable in its accuracy to the ankle brachial index. The study showed that about 1 in 10 people who don't have peripheral artery disease will be incorrectly told that they do when tested with the device. Those figures come from an evaluation of the device in just 15 patients.

Experts said that level of imprecision, combined with the small sample size, makes it problematic for use in widespread screening because of the potential that false positives could expose high numbers of patients to unnecessary care.

"If you have something that's very sensitive, but not perfectly specific, you're going to pick up a lot of people, and you're going to be able to upcode a lot of people," said Steven Nissen, a cardiologist at the Cleveland Clinic. "Before I would want this to be used widely, I would want better studies suggesting that it is accurate, that it's better than ankle brachial index, that it's cost-effective."

A UnitedHealth physician leader, whom the company made available only on the condition that he not be identified, said a study is underway to compare QuantaFlo to the ankle brachial index.

Doctors with expertise in managing artery disease said they would not diagnose a patient with peripheral artery disease based on a positive result from QuantaFlo alone, and would seek to confirm the finding with an ankle brachial test. Semler asserts that no such confirmatory testing is necessary.

"QuantaFlo PAD is a stand-alone test that supports clinicians in the early diagnosis of PAD and does NOT require confirmation by cuff-based ABI," the company says on its website.

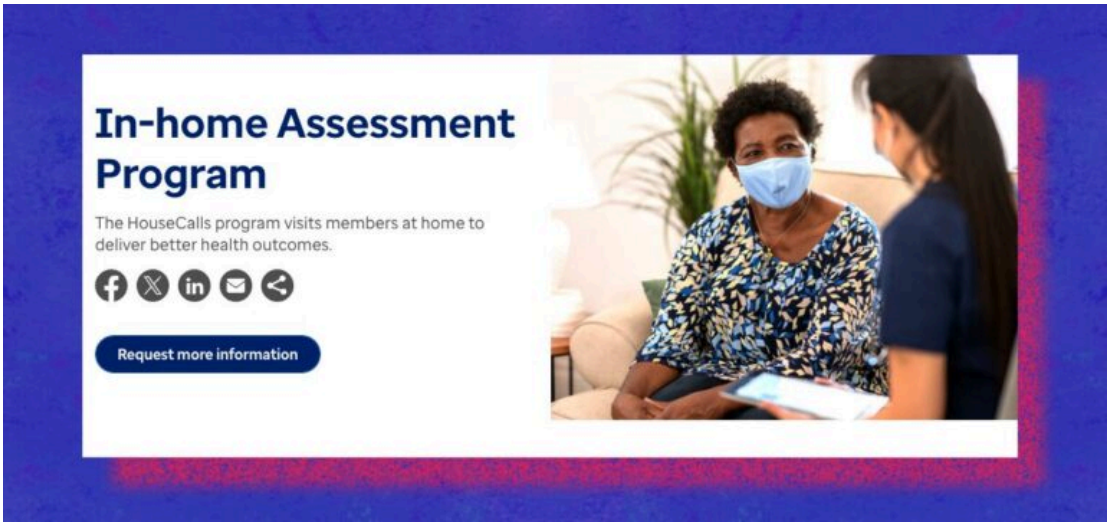
A Semler executive declined to respond to a detailed list of questions provided by STAT.

While QuantaFlo is used in some vascular clinics, its biggest customers are private insurers. Those companies were an early target for Semler, which focused on Medicare Advantage insurers because of the potential to boost use of the product nationwide.

Signify Health, a company owned by CVS Health that conducts home visits for Medicare Advantage insurers, also used the test on behalf of several large clients. A Signify spokesperson said the company uses QuantaFlo on patients with clinical risk factors for peripheral artery disease.

UnitedHealth began to expand testing nationwide through its HouseCalls program in 2017. The physician leader said the company's providers take into account the patient's medical history and findings from a physical examination, in addition to the results derived from QuantaFlo. An example scenario in guidelines for the program presents an 80-year-old woman with hypertension, no symptoms of peripheral vascular disease, and a positive QuantaFlo result. She would be coded with "peripheral vascular disease, unspecified."

UnitedHealth emphasizes in its marketing materials that early identification of chronic illnesses creates an opportunity to deliver more proactive and effective care. But years earlier, the company's executives focused on peripheral artery disease to seize a different kind of opportunity — one that directly benefited its bottom line.



UnitedHealth's HouseCalls program sends clinicians to millions of Medicare Advantage patients' homes nationwide to run tests. *STAT*

'Huge $ opportunities'

UnitedHealth's leaders set their sights on the financial opportunity tied to peripheral artery disease in 2007, after regulators revised Medicare Advantage's payment formula to account for patients' health status.

The change was based on a bedrock principle of the insurance business: Companies should be paid more for taking on more risk.

In November of that year, Jerry Knutson, then chief financial officer of UnitedHealthcare's Medicare and retirement division, flagged the money-making potential of vascular disease in an email to Jeffrey Dumcum, a senior vice president at Optum who worked in risk adjustment and now manages clinical performance and compliance. In his message, Knutson asked for a meeting with Dumcum to discuss ways to increase revenue from "risk-scoring" opportunities the two executives had discussed in prior conversations.

"You mentioned vasculatory disease opportunities, screening opportunities, etc with huge $ opportunities," Knutson wrote to Dumcum. "Lets turn on the gas! What can we do to make sure we are being reimbursed fairly for the members and risk we take on more than what we are currently doing."

The message, in which Knutson stated a desire to increase 2008 revenue by $100 million, was included in a federal whistleblower lawsuit filed by a former UnitedHealth financial manager, Benjamin Poehling, who had been copied on the email. Knutson is now chief financial officer of a chain of pediatric clinics in South Florida.

Poehling accused UnitedHealth's executives of bilking Medicare by failing to ensure the diagnosis codes it submitted to the agency were accurate. UnitedHealth has disputed the allegations and continues to fight them in court.

The case, scheduled for trial next year, was initially filed in 2011. After a five-year investigation, the Department of Justice joined the lawsuit in 2017, just as UnitedHealth began to expand its screening within its HouseCalls program to states across the country.

The divergent testing rates of artery disease within Medicare

Rate of non-invasive PAD testing per 10,000 people, by enrollment type

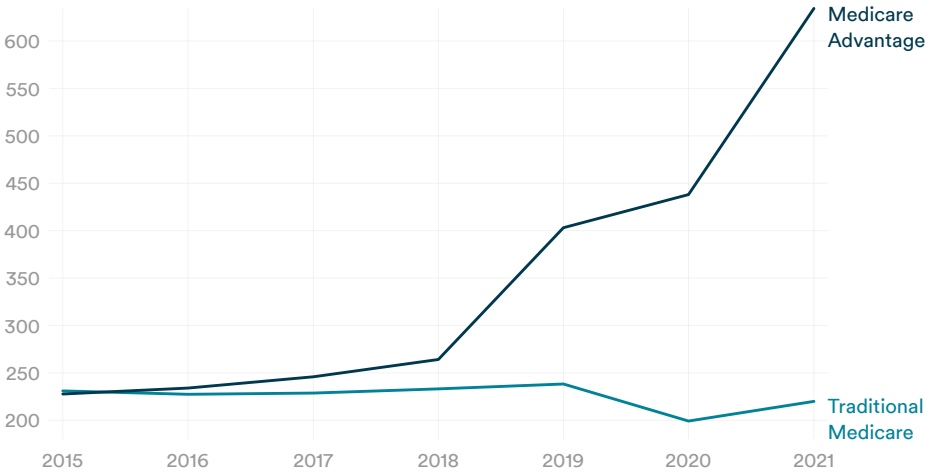


Chart: J. Emory Parker/STAT • Source: Lown Institute

As it ramped up testing with QuantaFlo, the company sought to generate evidence to support widespread screening.

Two separate studies, one on patients at a UnitedHealth-owned practice in Nevada, and another on a larger data sample drawn from its HouseCalls program, found that screening Medicare Advantage beneficiaries with QuantaFlo would find the condition in between 28% and 32% of patients. They also found that those who tested positive were more likely to die or experience heart attacks, strokes, and amputations in the ensuing years. But the studies were hardly independent — both were written by UnitedHealth employees.

Semler seized on the findings of the larger study in marketing materials. “We believe this study supports the use of QuantaFlo for PAD by customers who conduct in-home testing, which may drive further adoption by existing and new customers,” Doug Murphy-Chutorian, a physician and CEO of Semler Scientific, said in a December 2022 press release.

But authors of the studies disclosed important limitations: QuantaFlo’s accuracy in different populations was unknown, and it needed further validation as a relatively new and untested technology. To use it in widespread screening at that point was not a simple or obvious next step, said Carlos Mena-Hurtado, a Yale cardiologist who co-authored both of the studies.

“It’s kind of a big jump,” Mena-Hurtado said.

By the time the studies were published in 2022, UnitedHealth had already made that leap. At that point, the company also had a much larger network of physicians, having acquired large primary care practices nationwide, including in New York, Connecticut, Texas, Oregon, Florida, and Massachusetts. That created more opportunities for expanded testing.

UnitedHealth Group headquarters in Edina, Minn. *Tim Gruber for STAT*

The fallout

A plethora of devices have become staples of the annual physical — the arm cuff to measure blood pressure, the stethoscope to listen to hearts and lungs. But within UnitedHealth, a little lime-green clip started popping up in primary care clinics across the U.S.

The company introduced the green QuantaFlo clip to primary care doctors at ProHealth, a UnitedHealth-owned network of clinics in Connecticut, after the worst of the Covid-19 pandemic. The pitch was simple: If you use this test on Medicare Advantage patients, it will not only identify undiagnosed peripheral artery disease, but also increase patients' risk scores, allowing the organization to tap into a sea of revenue.

Each diagnosis was worth about $3,600 in extra payments from Medicare, depending on the age and sex of the patient, according to a STAT analysis of Medicare data reviewed by an outside expert.

The directive to test all Medicare Advantage patients fell in line with the screening-heavy playbook UnitedHealth subsidiary Optum had championed at ProHealth since buying the network in 2015. Still, the doctors at the primary care network were baffled, several of them later recalled in interviews with STAT. Where was the evidence to support the test, and why would they screen asymptomatic patients when the U.S. Preventive Services Task Force had recommended against it?

"We were clamoring for information," said Good, a former ProHealth primary care doctor. "They didn't have this in medical school or in residency. We've never heard of this test. What's its basis, what's its validity?"

The UnitedHealth physician leader told STAT the company has shared clinical research with physicians who have raised questions about QuantaFlo, and noted that skepticism comes with any new technology.

But five former ProHealth doctors said they never received a satisfying justification for using QuantaFlo from UnitedHealth. All told STAT they were concerned that patients with false or exaggerated PAD diagnoses would receive unnecessary treatments, like statins or blood pressure medications, and struggle to buy life or disability insurance policies.

“It requires a discussion,” Good said. “It’s not just, ‘Oh, you’re a human being who’s over the age of 65, let’s order a test for you.’ Everyone has a different situation, and every test has the possibility of negative consequences.”

Good, Rubin Hirsch, Craig Czarsty, and two other experienced doctors who worked at ProHealth said they resolved to ignore UnitedHealth’s demands to use the QuantaFlo test. But it wasn’t going to be that easy.

UnitedHealth controlled the physicians’ schedules and which patients would be seen by which doctors. Five clinicians said the company began to work around the doctors skeptical of the test, hiring nurse practitioners to conduct the test at annual wellness visits. One former ProHealth doctor said UnitedHealth started removing patients from their schedule and routing them to these nurses instead.

The result was chaos, the five doctors said. The nurse practitioners ordered QuantaFlo and other tests that racked up diagnostic codes, but were not allowed to offer clinical advice based on those results. The ProHealth doctors would then get calls from patients agonizing over the results.

“They’d call up and say, what does this mean that I have peripheral artery disease?” Good said. “What is this all about? Why didn’t you ever tell me about this?”

Michael Good, a former family medicine physician, with a doctor's bag he once used for house calls, at his home in Durham, Conn. Good retired from practicing at ProHealth Physicians in 2023. *Tim Tai for STAT*

Some of the QuantaFlo diagnoses were nearly useless, five ProHealth doctors told STAT. A cardiologist patient who regularly exercised, had no symptoms, and was on a statin received a positive test. He brushed it off, his doctor recalled. Another QuantaFlo diagnosis hit close to home when the father of one former ProHealth doctor received a positive test.

"For him, it had no effect whatsoever because I was able to explain it to him on the back end," the former ProHealth doctor said. "He's already on cholesterol medication, he's not having symptoms. And frankly, it was probably a false positive."

But not every patient is so well-informed or has a physician in the family. In the absence of sound primary care advice, patients started calling into local vascular clinics.

Over the past two years, vascular offices in central Connecticut started fielding phone calls from anxious patients who had received abnormal QuantaFlo results. Kristine Lane, a physician's assistant at The Vascular Experts, a vascular care chain with offices across Connecticut, said several patients called asking to be seen immediately, worried that they might eventually lose a leg without treatment. Some had been referred by ProHealth and from insurance company programs that sent clinicians to visit patients in their homes, including HouseCalls.

She said the clinic conducted an ultrasound on these patients to scan their lower extremities for signs of restricted blood flow. She couldn't recall a single follow-up test that found evidence of disease. "They'll come in with an extremely abnormal QuantaFlo number, and then on real testing — more elaborate testing — they're not abnormal at all," she said.

The same pattern unfolded at a nearby vascular clinic at Hartford HealthCare, to the point where clinical staff stopped ordering normal follow-up testing because so many QuantaFlo patients were falsely positive. They would often come in with strong pulses in their feet, an employee said.

The test is tying up vascular and primary care clinics not only in Connecticut, but also across the country. UnitedHealth's HouseCalls program is nationwide, with millions of Medicare Advantage patients allowing the insurer's clinicians into their homes to run tests.

In Littleton, North Carolina, family physician Ray Antonelli sees about three or four patients a week who are reeling with anxiety after receiving a positive QuantaFlo test during a UnitedHealth wellness visit. He recalled seeing a patient who was convinced she had peripheral artery disease because the results said "Normal/Borderline," even though she wasn't experiencing any symptoms. The misunderstanding ate into precious time needed for discussing more pressing health issues.

"I usually use some kind of analogy like, we try not to dredge up problems if it's not going to be helpful to you," Antonelli said.

Foluso Fakorede, a Mississippi cardiologist and leader in peripheral artery disease treatment, said he's noticed a major uptick in QuantaFlo patients referred to his office. Like the vascular doctors in Connecticut, he typically ignores the test result if patients' pulses feel normal and they have no risk factors. "A couple of times, I have not charged a patient for a visit because I just feel bad," Fakorede said.

Fakorede is on the frontlines of the fight against an amputation epidemic that primarily affects Black Americans, whose PAD often goes undiagnosed until it's too late. He and other vascular doctors have been ringing the alarm on this issue for years, calling for more accessible and affordable screening. He acknowledged that QuantaFlo isn't perfect — but his concern lies less with the test, and more with the way UnitedHealth is deploying it.

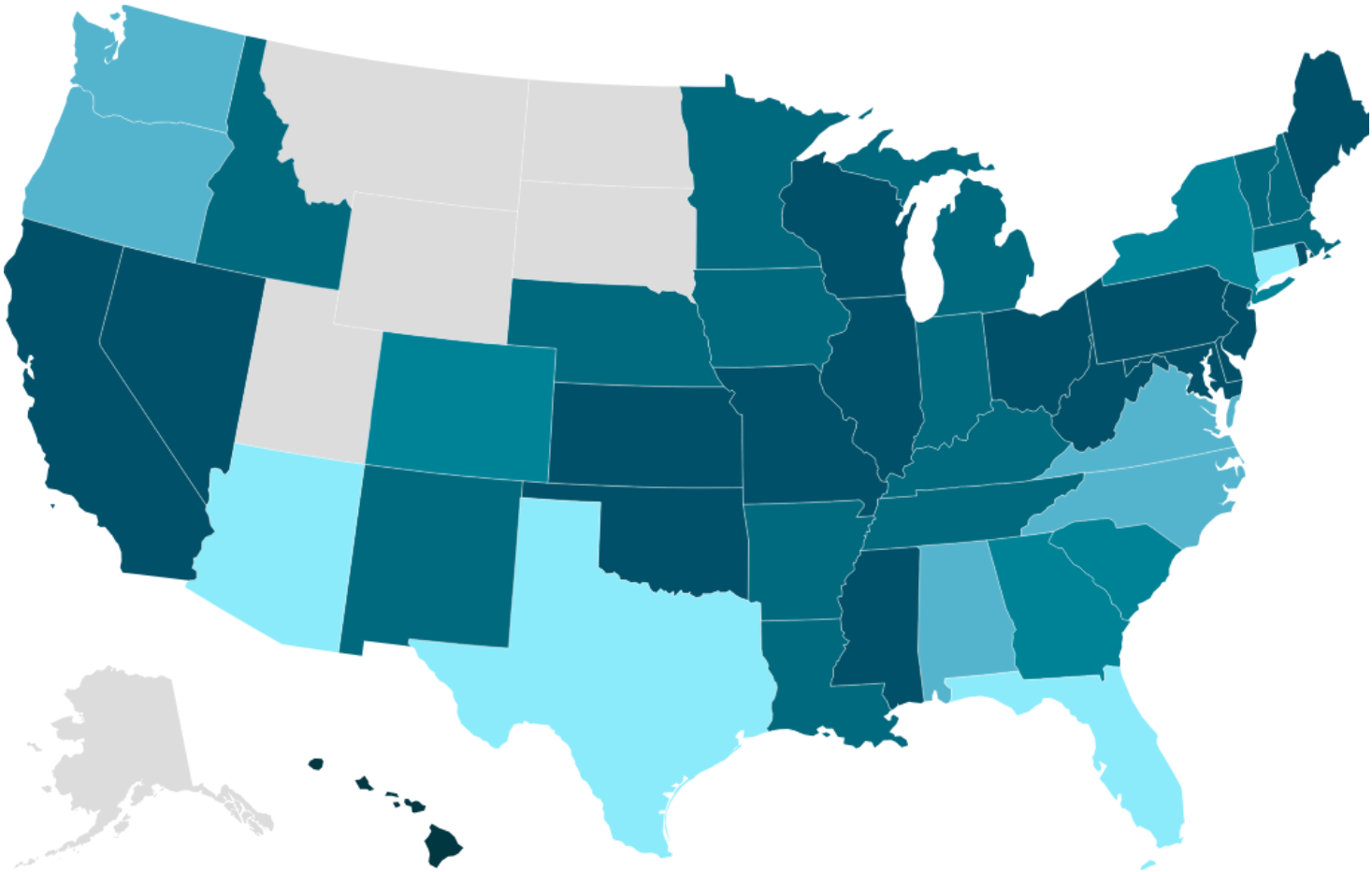
Watching Medicare Advantage patients flood into his clinic, he's skeptical that insurers like UnitedHealth are committed to taking care of the patients whose risk score money they eagerly collect. Securing reimbursement for a procedure on a sick PAD patient is still extraordinarily difficult, he pointed out.

"Is it that we want to increase the pool of the patients in the Advantage plans that have chronic disease states, but we do not want anything coming out of the pool to really treat these patients?" Fakorede asked.

UnitedHealth's nationwide focus on coding artery disease

When Optum began in-home visits with peripheral artery disease screening, by state

April 2017 May 2017 August 2017 November 2017 January 2019 February 2019



Note: Among Medicare Advantage beneficiaries
Map: J. Emory Parker/STAT • Source: Smolderen et al., AJPM Focus (2022)

A dramatic rise in coding for PAD

Testing for peripheral artery disease began to skyrocket within Medicare Advantage in 2018, the first full year after UnitedHealth instituted QuantaFlo screening in its HouseCalls program in 26 states, from Connecticut to Colorado.

An analysis of Medicare data conducted for STAT by the Lown Institute, a nonpartisan health research organization, found that the rate of non-invasive PAD testing using QuantaFlo and other products climbed among Medicare Advantage patients from about 250 tests per 10,000 beneficiaries in 2018 to 650 per 10,000 by 2021. Meanwhile, the rate of testing within traditional Medicare dropped slightly, to just over 200 tests per 10,000, according to the analysis. Because of different reporting requirements, the Medicare Advantage data are incomplete and likely undercount the rate of testing.

From 2018 to 2021, UnitedHealth tallied more than 1.3 million unspecified artery disease diagnoses, according to Lown's analysis. The code for that diagnosis is worth roughly $3,000 annually on average, according to federal Medicare experts, meaning UnitedHealth took in approximately $4 billion in taxpayer money from both valid and questionable PAD diagnoses during that four-year stretch.

UnitedHealth's own data, published in late 2022, showed the company's clinicians diagnosed Medicare Advantage patients with peripheral artery disease at almost four times the rate of patients in traditional, government-run Medicare, which does not provide the same financial incentives.

UnitedHealth researchers argued in their study that more careful management of patients led to lower costs and better outcomes, including lower odds of hospitalization and fewer emergency department visits and admissions for heart attacks and strokes. In an interview with STAT, the UnitedHealth physician executive also said that Medicare Advantage's payment system rewards insurers for catching and managing chronic conditions early.

But former Medicare officials argued there was no direct evidence that the increased rate of diagnosis of peripheral artery disease was leading to better care — and it was causing costs to skyrocket. "[Medicare's] risk adjustment system has allowed plans to in effect set their own premium by incessantly creating, hunting for, and submitting more diagnosis codes to CMS," stated a March 2023 letter signed by 19 former Medicare officials, physicians, and policy experts.

The flood of codes for the illness and other chronic conditions, such as kidney disease and substance use disorder, dramatically boosted reimbursements to Medicare Advantage insurers, resulting in excessive payments expected to cost taxpayers $50 billion this year alone, according to the Medicare Payment Advisory Commission.

The letter supported reforms CMS ultimately enacted to eliminate the diagnostic code for peripheral artery disease without complications, among other changes. A CMS spokesperson told STAT the agency made those changes after it "carefully reviewed what we use in the model to predict costs and took a close look at where coding of diagnoses is likely not consistent across the industry."

Practices in the industry appeared to shift when CMS announced its coding changes. Testing and diagnosis for the condition began to drop, according to an analysis of provider records conducted for STAT by Truveta, a health data company. The rate of testing and diagnosis in patients 50 and older more than doubled between 2018 and 2023 — from 7 per 100,000 patients to 14.7 per 100,000, then fell to 9.6 in May 2024.

After Medicare revealed its plan to change coding, Semler announced its intent to use QuantaFlo to diagnose "heart dysfunction." In a recent earnings call, Semler's Chief Financial Officer Renae Cormier said the company hopes to achieve FDA clearance in the second half of 2024. Meanwhile, Semler is pouring its QuantaFlo profits toward a completely different endeavor — buying up $63 million worth of bitcoin since May.

QuantaFlo screenings seem to be on the way out at ProHealth. In March 2024, management told providers that the test would not be a covered benefit under a Medicare Advantage provider network in Connecticut, according to a copy of the email obtained by STAT.

"Please do not leave patients with the expectation that they will receive QuantaFlo screening as part of their Embedded Nurse Practitioner visit," the email reads.

But the effects are still rippling through the community. Several ProHealth doctors who STAT spoke with retired at least five years earlier than they planned, dismayed by the decisions UnitedHealth made to escalate profits at the expense of patients — the use of QuantaFlo among them.

"Patients were told these were things their doctors recommended," Good said. "It was a betrayal of our patients' trust."

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Health Care's Colossus: Share your experience

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